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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,269	07/19/2005	Fabio Giannessi	2801-140	1068
23117 7590 04/23/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER CUTLIFF, YATE KAI RENE	
			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		04/23/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

10/537,269

**Applicant(s)**

GIANNESI ET AL.

**Examiner**

Yate K. Cutliff

**Art Unit**

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-16 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Specifically, due to the numerous variables in the claims, i.e. Z for the derivatives of guanidine, and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I, claims 1, 5, 7, 8 and 9, in part, drawn to the compound and composition, thereof of formula I, with Z as defined in claim 2 and Q, W, X, and Y are defined in claim 1.

Group II, claims 1, 5, 7, 8 and 9, in part drawn to the compound and composition, thereof of formula I, with Z as defined in claim 3, and Q, W, X, and Y are defined in claim 1.

Group III, claims 1, 5, 7, 8 and 9, in part, drawn to the compound and composition, thereof of formula I, with Z as defined in claim 2, X and Y as defined in claim 4; and Q and W are defined in claim 1.

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Group IV, claims 1, 5, 7, 8 and 9, in part drawn to the compound and composition, thereof of formula I, with Z as defined in claim 3, X and Y as defined in claim 4; and Q and W are defined in claim 1.

Group V, claims 1, 5, 7, 8 and 9, in part, drawn to the compound and composition, thereof of formula I, with Z not being defined as in Groups I – IV above and X and Y as defined in claim 4; and Q and W are defined in claim 1.

Group VI, claims 13- 16, drawn to a method of treating utilizing a compound from Group I.

Group VII, claims 13- 16, drawn to a method of treating utilizing a compound from Group II.

Group VIII, claims 13- 16, drawn to a method of treating utilizing a compound from Group III.

Group XIV, claims 13- 16, drawn to a method of treating utilizing a compound from Group IV.

Group X, claims 13- 16, drawn to a method of treating utilizing a compound from Group V.

Therefore, the claims herein lack unity of invention because lack of unit exist between all of the various combinations.

2. The inventions listed as Groups \*\*\* do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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Each of Groups I – X contain the genus of formula (I), which is the significant structural element that is shared by all of the analogous compounds. However, Wilkinson-Berka et al.: "ALT-946 and Aminoguanidine, Inhibitors of Advanced Glycation, Improve Severe Nephropathy in the Diabetic Transgenic (mREN-2) 27 Rat", Vol. 51, 2002, page 3283, (see PTO-1449, filed June 1, 2005) which includes the features of applicant's genus for formula I. Specifically, formula I of applicant's invention is lacking novelty because it reads on Wilkinson-Berka et al., when  $n = 0$  and Q, W, X, Y and Z are selected from H. Wilkinson-Berka et al is factual evidence that the technical feature lining each of the inventions is no longer considered a special technical feature at the time of the filing of applicant's application. Because applicant's genus of formula I, is known in the art it is not a special technical feature and the claims of Groups I – X lack unity of invention.

Accordingly, Groups I – X are not so linked by the same corresponding special technical feature as to form a single general inventive concept.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

#### **Notice of Possible Rejoinder**

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yate K. Cutliff whose telephone number is (571) 272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tssang can be reached on (571) 272 - 0562 or Janet Andres at (571) 272 - 0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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**PRIMARY EXAMINER**

